UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNTED STATES OF AMERICA et al.
ex rel. JULIE LONG,
Plaintiffs,

v. CIVIL ACTION NO. 16-12182-FDS

JANSSEN BIOTECH, INC.,
Defendant.

MEMORANDUM AND ORDER ON RELATOR'S
MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS AND
A COMPLETE AND PROPER PRIVILEGE LOG (#223)

KELLEY, U.S.M.J.

I. Introduction.

This is a *qui tam* action alleging that a pharmaceutical company unlawfully provided free business advisory services to physicians who prescribed its medications, in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and caused physicians to submit false claims for reimbursement to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a). Relator Julie Long alleges that Janssen Biotech, a company that manufactures and sells two infusible drugs, Remicade and Simponi ARIA, improperly employed teams of practice advisors, including relator, and hired outside consultants to provide services such as presentations, advice, and customized analyses to doctors to assist them in running profitable infusion businesses ("in-office infusion suites," or "IOIs").

The facts of the case and a detailed analysis of the claims in the Second Amended Complaint (#55) are set out in Chief Judge Saylor's Order and Memorandum on Defendant's Motion to Dismiss (#75) and will only be repeated here as necessary to put the discovery motions at issue in context. In addition, this court recently issued an order concerning other discovery matters (#282) which sets out the background concerning discovery in this case in detail, which will not be repeated here.

II. Relator's Motion.

Relator moved for the following discovery:

1. A complete privilege log identifying all documents withheld under a claim of privilege and providing sufficient detail to enable Plaintiff to assess the propriety of the privilege asserted;

2. Requested documents that are in the possession of current and former employees known to have discoverable information;

3. Documents responsive to Requests for Production 8 and 21-27 located in its corporate files and possessed by current and former employees known to have discoverable information;

4. All documents responsive to Requests for Production 4, 6, 7, 16, 31 and 34; and

5. All relevant documents in Karen Trahan's and Plaintiff's electronic files that pre-date October 28, 2006.

(#224 at 1.)

A. Relator's Request for a Complete and Proper Privilege Log.

Relator complains that Janssen has not provided it with a complete and "sufficiently descriptive [privilege] log." (#224 at 8.) First, relator says, Janssen has not logged all of the legal advice it received concerning the lawfulness of the programs at issue and whether Janssen knew that providing the support was unlawful. *Id*. at 10. Second, the privilege log that Janssen did supply, *see* #224-3, is deficient in several respects. (#224 at 10.)

In a recently-filed order, the court addressed the question whether Janssen has to search for legal advice and create a privilege log for all privileged communications concerning the programs at issue here over a period of many years. (#282 at 16.) In attempting to balance relator's need to discover materials pertaining to whether Janssen knew that it was engaging in unlawful activity with the proportionality factors set out in Federal Rule of Civil Procedure 26(b)(1), and mindful that while phase one discovery needs to be robust but that at this stage of the case discovery will not be complete for all purposes of the case, the court resolved this issue by ordering that relator could choose three custodians who provided legal counsel and Janssen would search their documents and provide a privilege log. *Id*. Thus, the court declines to order Janssen to search all files company-wide for this information at this time; relator's motion is denied in that respect.

Federal Rule of Civil Procedure 26(b)(5) provides that when a party withholds otherwise discoverable information by invoking privilege or work product, it must "describe the nature of documents, communications, or tangible things not produced or disclosed—and do so in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim." Fed. R. Civ. P. 26(b)(5). "Privilege logs do not need to be precise to the point of pedantry." *In re Grand Jury Subpoena*, 274 F. 3d 563, 576 (1st Cir. 2001).

The court finds that the privilege log that Janssen has already supplied is sufficient. It lists the date of each document, the individuals involved in the communications, and the nature of the privilege asserted. *See Bryan Corp. v. Chemwerth, Inc*., 296 F.R.D. 31, 41 (D. Mass. 2013) (finding a log adequate where it contained a similar level of detail). It is not clear to the court what further "fact-specific" information Janssen is to produce. For example, one description from the log, "email chain reflecting legal advice regarding preparation/review of internal training or internal guidance concerning practice management or IOI support" (#224-3 at 8) allows relator to know

that the contents of the communications reflect legal advice about training or guidance concerning IOI support. No more is needed.

Relator is entitled to know who the parties are in each communication and what their roles were in the company. Relator's motion regarding the privilege log is otherwise denied.

B. Requested Documents In the Possession of Current and Former Employees.

This request was discussed at length in the court's recent order (#282 at 15), and for the reasons set out there, it is allowed.

C. Specific Requests for Production of Documents from Corporate Repositories or Employees of Janssen.

Relator complains that Janssen did not search its corporate repositories or the files of employees who had significant involvement in the provision of IOI support in response to certain requests for production ("RFPs"). (#224 at 16.)[1] As mentioned above, the court recently issued an

[1] The RFPs relator lists are as follows:

RFP 8: Management-Level Documents sufficient to show the factors or criteria that determined how frequently IOI Accounts (including the Phase 1 Accounts) received IOI Support.

RFP 21: All Management-Level Documents concerning the returns or benefits that you derived from providing the IOI Support.

RFP 22: All Management-Level Documents concerning the benefits or value that IOI Accounts derived from the IOI Support.

RFP 23: All Management-Level Documents concerning the answers, results, and findings from surveys and market research concerning the benefits or value that IOI Accounts derived from the IOI Support.

RFP 24: All Management-Level Documents concerning the purpose, reason, or objective of providing the IOI Support.

RFP 25: All Management-Level Documents concerning the use of the IOI Support to: (a) Grow or maintain Remicade and/or Simponi ARIA utilization or sales; (b) Cause or influence physicians to commit to or increase their confidence in the infusion business model or Remicade business model.

RFP 26: All Management-Level Documents concerning the influence, effect, or impact that providing IOI Support had on IOI Accounts' utilization of Remicade or Simponi ARIA.

order agreeing with relator that Janssen must make a reasonable inquiry and undertake a reasonable effort to produce requested documents possessed by current and former employees who had significant involvement in the development, review, approval, monitoring, and/or delivery of the support services at issue in this case, whether or not relator happened to name such employees as ESI custodians. (#282 at 15.) The court assumes that that order will resolve the issues raised by relator with regard to the specific RFPs here. The court credits Janssen's assertion that documents responsive to these RFPs are not found in corporate repositories. (#232 at 10.)

D. RFP Nos. 4, 6, 7, 16, 31, and 34.

1. Janssen's Relevant Compliance Policies and Guidance.

Relator complains that Janssen has not provided all of the requested compliance guidance and policies. (#224 at 18.) The requested documents are certainly relevant and discoverable. The court credits Janssen's response that it continues to look for such documents and is producing them. (#232 at 11.)

2. Reports That Tracked Critical Information About the Accounts in Pennsylvania.

Relator complains that Janssen refuses to provide documents that show or track certain information about the accounts in Pennsylvania at issue here, such as whether Janssen assisted in opening an IOI; when a certain practice opened or closed an IOI; and detailed information about

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> RFP 27: All Management-Level Documents concerning the ability to effect change in IOI Accounts or influence IOI Accounts to perform more Remicade and/or Simponi ARIA infusions through Managing Biologics in the Physician Office (MBPO), Account Rev view, IBiz, Infusion Optimization Modeler (IOM), and/or Infusion Services Review (ISR) consultative sessions.

(#224 at 16-17.)

the support provided and the business generated by the practice.[2] (#224 at 18-19.) Janssen responds that "it has produced all the information *from centralized databases* that is responsive to RFP 16, including the available raw sales data for the eleven Phase 1 Accounts, sales data purchased from third party IQVIA, and database materials in Access database format for entries by Julie Long or Dana Griffith or any of the Phase 1 Accounts between October 2006 and February 2016." (#232 at 12.) (emphasis added). In addition, Janssen has produced information responsive to some of this request gleaned from the documents of the present custodians. *Id*.

Janssen is not limited, however, to looking in "centralized databases" for this information. The court orders Janssen to make a reasonable effort to collect the information pertaining to the

[2] Specifically, in RFP 16, relator requested that Janssen produce: "All documents that show or track the following information for any and all of the Phase 1 Accounts:

> (a) Whether you assisted the account with opening the IOI;
> (b) When the account opened its IOI;
> (c) If applicable, when the account closed its IOI;
> (d) Each occasion an ABS or Outside Consultant called on or visited the account;
> (e) Each occasion an ABS or Outside Consultant provided a dinner or lunch program;
> (f) Each occasion an ABS or Outside Consultant provided any IOI Support;
> (g) Each occasion an ABS provided a Managing Biologics in the Physician Office (MBPO), Account Review, IBiz, Infusion Optimization Modeler (IOM), and/or Infusion Services Review (ISR) consultative session;
> (h) Remicade and Simponi ARIA utilization volume;
> (i) Utilization volume of Competing Drugs (collectively or individually);
> (j) Each occasion the account committed to the ABS that it would prescribe Remicade and/or Simponi ARIA to additional patients;
> (k) Each occasion the account committed to the ABS that it would increase infusion capacity or volume;
> (l) The number of Medicare patients prescribed Remicade, Simponi ARIA, or a competing drug or biologic;
> (m) Claims for reimbursement submitted to Medicare (including Medicare Advantage) for Remicade or Simponi ARIA and related infusion procedures;
> (n) Payer mix.

(#224 at 18-19.)

accounts in question in Pennsylvania, starting on the date when Janssen began providing IOI support to the physician practices in Pennsylvania, from other sources.

3. Janssen's Communications with the Government.

Relator argues that Janssen must provide "what information Janssen disclosed to U.S. Department of Justice concerning this action" and "whether Janssen ever sought guidance or an advisory opinion from HHS-OIG [Health and Human Services Office of Inspector General]." (#224 at 20.) In addition, "[b]ecause Janssen has asserted a materiality defense, it should be required to produce any communications it had with Medicare concerning its provision of the IOI Support to physician practices." *Id*.

Chief Judge Saylor previously denied Janssen's request for a protective order concerning "Janssen's communications with the U.S. Government concerning (1) the Civil Investigative Demand served on Janssen on March 27, 2017, and the related investigation and (2) whether Janssen ever sought guidance or an advisory opinion from HHS-OIG concerning [the use of ABSs to advice physician practices with respect to infusion products]." (#221 at 1-2.) The information sought by relator is relevant and discoverable, as this court recently noted in its previous orders (#282 at 13-14; #283 at 5, 7-8).

Janssen, while not arguing that relator's request should be denied, argues that "communications identified in [the present] custodians' files or corporate repositories that were relevant and responsive to this request" have been produced. (#232 at 13.) As the court stated in its recent order, however, Janssen must not confine itself to corporate repositories or the present custodians in searching for discovery. (#282 at 15.) Relator's request, including with regard to communications with Medicare, is allowed.

4. Job Descriptions for Positions That Had Significant Involvement in IOI Support.

In RFP 4, Relator requested

> Management-Level Documents sufficient to show the responsibilities of the following positions (or their equivalents) related to the promotion or support of Remicade and Simponi ARIA: ABS, Regional Business Manager, Regional Business Director, Regional Business Coordinator, Remicade Product Manager, Remicade Product Director, Infusion Group Product Director, Business Development Manager, Vice President Immunology Sales, Director of Marketing Immunology, Immunology Sales Specialist, and Medical Science Liaison.

(#224 at 21.)

Relator argues that "[t]he job descriptions for all positions where the employees had significant responsibility for the development, review, approval, delivery, or oversight of the IOI Support are highly relevant because the job descriptions summarize witnesses' specific roles concerning the IOI Support. This discrete group of core documents is proportionate to the needs of the case." *Id*. The court agrees. Janssen has indicated that it is searching for whether it has any job descriptions that it has not yet found that can be turned over. (#232 at 14.)

5. Contracts with Outside Consultants.

In RFP 7, relator requested that Janssen produce: "All contracts or agreements between you and any Outside Consultant related to: (a) providing advice or information to IOI Accounts; or (b) creation of presentations or programming utilized by ABSs in connection with providing IOI Support." (#224 at 21.) The court limits this request to the accounts in question in Pennsylvania. Janssen replies that it has made a reasonable search for these documents. (#232 at 14.) The court orders Janssen to provide the documents it finds after a reasonable search, going back to the start of the programs in question in Pennsylvania.

6. Document Retention Policies.

In RFP 6, relator requested that Janssen produce: "All documents concerning your policies and practices regarding document retention, document destruction, records management, disaster recovery, and litigation holds." (#224 at 22.) Janssen limited its production to its current document retention policy. *Id*. Relator argues that although the current policy is relevant, the policies that were in place at the time Janssen learned of this litigation are far more relevant. *Id*. at 22-23. The court agrees, and such information should not be difficult for Janssen to locate and produce. Janssen is ordered to produce prior versions of its document and retention policies.

7. Karen Trahan's and Relator's Electronic Files Pre-Dating 2006.

Janssen provided documents from relator's and a custodian, Karen Trahan's, files starting in October 2006. Relator argues that Karen Trahan, who worked as a Regional Business Manager for the Eastern United States, including Central Pennsylvania, from 2000 to 2015, is "one of the most important witnesses in this case." (#244 at 22.) Relator states that Ms. Trahan "had substantial involvement in the development and oversight of the IOI Support Janssen provided to physician practices in Central Pennsylvania." *Id.* Relator argues that the documents from Ms. Trahan's and relator's electronic files that pre-date October 28, 2006, are "critical to understanding the development of the various types of IOI Support Janssen provided to physician practices in Central Pennsylvania after October 2006" and "will provide important information concerning when, why, and how Janssen began providing the IOI Support to physician practices in the bellwether territory." *Id*. at 23.

Janssen argues that these documents are "outside the Court-ordered timeframe." (#232 at 14.) It further argues that relator may depose Ms. Trahan concerning her involvement in the inception of the IOI support programs at issue here. *Id*. at 15.

The court agrees with relator that, for these two custodians, there is good reason to make an exception to the court-ordered cut-off period of 2006. The court credits relator's statement that Ms. Trahan is a key witness. The court already provided exceptions to the 2006 date concerning the development of programs, extending the time period for discovery "back to the time the program[s] [were] devised." (#120.) Further, the deposition of Ms. Trahan concerning events far back in time will be difficult, if not impossible, without discovery of documents from the distant time period in question. Relator's motion is allowed as to this request.

III. Conclusion.

For the above reasons, relator's motion to compel and for the production of a complete and proper privilege log (#223), is ALLOWED in part and DENIED in part.

February 17, 2022

/s/ M. Page Kelley
M. Page Kelley
United States Magistrate Judge